administering to a population of individuals a pharmaceutical composition according to claim 9 to reduce the occurrence of HBV infections in the population.--

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claims are allowed. Claims 5-12, 15-17, and 19 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

The examiner indicates that the use of trademarks have been noted in this application. Appropriate amendment is made to the specification. It is pointed out that lines 12-14 on page 5 provides generic terminology for ENGERIX-B. Applicants have also amended the specification at page 5, line 14 to add a further description of this trademarked vaccine, as evidence by the attached copy of the U.S. prescribing information for ENGERIX-B from the manufacturer.

The unreadable text on pages 4, 9 and 10 is corrected and appropriate corrections to the abbreviation "HB" and "o.n." are made to the specification. However, with regard to "ad antigen", applicants clarify that this is not an abbreviation. Rather, "ad" is a determinant of the genetic variability of HBsAg. There is a common determinant "a" and

two pairs of mutually exclusive determinants "a" and two pairs of mutually exclusive determinants "d/y" and "w/r" which enable the distinction of four major subtypes of HBsAg, "adw", "adr", "ayw" and "ayr". See page 15, lines 13-19. Accordingly, reconsideration and withdrawal of the requirement to correct the specification with respect to "ad antigen" as an abbreviation is respectfully requested.

In response to the Notice to Comply with the Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino acid Sequence Disclosures, applicants have added into the present specification a new paper copy Sequence Listing section according to 37 C.F.R. §1.821(c) as new pages 1-4. Furthermore, attached hereto is a 3 ½" disk containing the "Sequence Listing" in computer readable form in accordance with 37 C.F.R. §1.821(e).

Applicants have amended the specification to insert SEQ ID NOs, as supported in the present specification.

The following statement is provided to meet the requirements of 37 C.F.R. §1.821(f) and 1.821(g).

I hereby state, in accordance with 37 C.F.R. §1.821(f), that the content of the attached paper and computer readable copies of the sequence listing are believed to be the same.

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I hereby also state, in accordance with 37 C.F.R. §1.821(g), that the submission is not believed to include new matter.

Claims 5-18 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The examiner states that a deposit of biological organisms is required for enablement of the current invention. The examiner acknowledges the deposit of organisms under ECACC Accession Nos. 96052170 and 96052168 in partial compliance with the requirements. However, the examiner holds that the deposits are not in full compliance with 367 CFR 1.803-1.809.

This rejection is obviated by the attached executed Declaration of Biological Material Deposit.

Claims 9, 11, and 13-18 have been rejected under 35 U.S.C. §112, first paragraph, because the examiner states that specification, while enabling for treatment of HBV infection, does not reasonably provide enablement for prevention of HBV infection. The examiner indicates that the rejected claims are drawn to prophylactic antibody vaccine compositions. The examiner further indicates that no protective immunity was demonstrated in the specification as there was merely a

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reduction in the number of infected animals not a prevention of HBV infection.

This rejection is obviated by the cancellation of claims 13, 14 and 18 and the amendment to claims 9, 11, 15, and 17 to delete recitation of "prevention". Claims 9, 11, 15-17 as amended and new claim 19 recite "reducing the occurrence of HBV infections in a population of individuals" instead of "prevention". Clearly, these new and amended claims are enabled by the disclosure in the specification of a reduction in the number of infected animals.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 1-6 and 9-18 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

This rejection as it relates to claims 1-6, 9, 11-16 and 18 is obviated by the cancellation of claims 1-4, 13, 14, 18 and the amendments to claims 5, 6, 9, 11, 12, and 15.

With regard to claims 10 and 17, which the examiner finds to be indefinite by the use of the term "therapeutically effective amount", the examiner states that it is unclear what the applicants are claiming, i.e., what threshold must be achieved in order to be deemed "effective". The examiner takes the position that, as written, it is impossible to determine the metes and bounds of the claimed invention. Furthermore, the examiner indicates that claim 17 is rendered

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indefinite by the use of the phrase "any one of claims 9". This part of the rejection is respectfully traversed.

Claims 10 and 17 are amended to recite administering "a therapeutically effective amount ... to treat HBV infection". The decision of the Court of Customs and Patent Appeals in *In re Watson*, 186 USPQ 20 (CCPA, 1975), held that:

> Frederiksen is authority for the proposition that the phrase "an effective amount" is indefinite when the claim fails to state the function which is to be achieved. The appealed claims in Frederiksen recited "an effective amount of the diethylamino ethanol ester of phenaaceturic acid". The claim completely failed to state the effect sought to be produced.
>
> The present case is distinguishable, however, since claim 1 recites "an effective amount of a germicide suitable for use in oral hygiene". The very term "germicide" used in this claim, indicates that germicidal action is the effect sought to be produced. Hence, the recitation points out both the effect sought to be produced and the purpose of that effect, viz., germicidal action in oral hygiene.
>
> Moreover, the claim language must be read in light of the application disclosure as it would be interpreted by one of ordinary skill in the art... Those skilled in the art will be able to determine from the disclosure, including the examples, what an effective amount of germicide is... In the context of the claimed subject matter, the disputed phrase reasonably defines the metes and bounds of the invention to one of ordinary skill in the art. We hold that claims 1, 2, and 4-6 are not indefinite under §112, second paragraph.

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Accordingly, the recitation of "therapeutically effective amount" in claims 10 and 17 is not indefinite because the recitation points the effect sought to be produced and the purpose of that effect. On the matter of the phrase "any one of claims 9", this recitation was deleted by the preliminary amendment filed with the application and replaced with "claim 9".

Claims 1-4 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Marcus et al. in view of Ichimori et al. This rejection is obviated by the cancellation without prejudice of claims 1-4.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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